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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,504	06/05/2001	Tugrul T. Kararli	6794S-00005	6698
7590 06/17/2004				
Donald R Holland Harness Dickey & Pierce Suite 400 7700 Bonhomme Clayton, MO 63105		EXAMINER OH, SIMON J		
		ART UNIT		PAPER NUMBER
		1615		
DATE MAILED: 06/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/874,504	KARARLI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Simon J. Oh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black (EPO Document No. 0 863 134 A1) in view of Guess *et al.* (U.S. Patent No. 6,054,455), and Bagchi *et al.* (U.S. Patent No. 5,662,883)

The Black application teaches synthesis of 2-(3,5-difluorophenyl)-3-(4-(methylsulfonyl)phenyl)-2-cyclopenten-1-one, a COX-2 inhibitor, and its formulation into a pharmaceutical composition by wet granulation techniques (See Methods A through C and Examples 1 through 2c, all on Pages 11-19). Other pharmaceutical forms, such as tablets and aqueous or oily suspensions are also disclosed (See Page 4, Lines 10-12). Uses of a composition comprising 2-(3,5-difluorophenyl)-3-(4-(methylsulfonyl)phenyl)-2-cyclopenten-1-one through oral administration, preferably in a once- or twice-a-day treatment are also discussed, as well as the various conditions that such treatment could alleviate (See Page 3, Lines 8-10 and 29-46; and Page 5, Lines 22-29). The use of the aforementioned active agent in conjunction with other active agents, such as caffeine is also disclosed (See Page 3, Lines 47-56). Specific dosages, ranging from 10 mg to 250 mg, are discussed as well (See Page 5, Line 30 to Page 6, Line 5).

The Black document is silent with respect to the use of valdecoxib in the composition, to the limitation regarding particle size of cyclooxygenase-2 inhibitory drug, and to the specific bioavailability features of a composition containing such a drug.

The Guess *et al.* patent is relied upon as a teaching reference, solely in order to illustrate that celecoxib, parecoxib, and valdecoxib are known in the prior art, as being among a group of selective COX-2 inhibitors (See Column 33, Lines 17-20).

It would be obvious to one of ordinary skill in the art at the time the invention was made, to combine the teachings of Black and Guess *et al.* into the invention of the instant application. Black teaches compositions with specific COX-2 inhibitors as the active substance, along with suitable dosages. The benefit of a COX-2 inhibitor composition in a once-a-day formulation is explained as well. Black also teaches how such COX-2 inhibitor compositions could be used to provide analgesia for various types of pain. It is the position of the examiner that the limitations in Claims 1 and 3 drawn to bioavailability features of the claimed invention do not impart a patentably distinct property to the claimed invention. Bagchi *et al.* give a broad teaching regarding the importance of reliable bioavailability in the administration of a drug. Bagchi *et al.* also disclose that based on the available technology at the time, particle sizes ranging from as low as about 1 micron to about 50 microns may be achieved (See Bagchi *et al.*; Column 1, Lines 10-45). Hence, Bagchi *et al.* disclose merely one way, and the motivation to do so, in which one of ordinary skill in the art can make adjustments in the formulation of drug compositions in order to achieve the desired bioavailability of the active ingredient. It is the position of the examiner that the selection of suitable drug particle sizes, down to particle size ranges claimed by the applicant using technology disclosed in Bagchi *et al.*, for the purpose of manipulating the

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bioavailability of an active ingredient, is within the purview of one of ordinary skill in the art at the time the claimed invention was made.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-58 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-58 of copending Application No. 10/113157. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

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